Glossary list for Researchers

Abbreviation	Definitions
ADR	**Adverse Drug Reaction** - Adverse drug reactions concern noxious and unintended responses to a medicinal product.
AE	**Adverse Event** - Any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product.
AI	**Associate Investigator**, also known as sub-investigator or a co-investigator - Any individual member of the research study team designated and supervised by the investigator at a site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows).
Amendments	An amendment must be submitted when there is any change to the current approved project, e.g.: change in research team, extension of ethical approval, change in protocol, update to safety or any document approved by an ethics committee.
Annual Safety Report	For clinical trials involving an investigational drug or device an Annual Safety Report must be submitted for ethics review to the reviewing Ethics Committee. For Investigator Initiated Trials this can be submitted with the annual progress report. The report should be attached as an appendix. For Commercially Sponsored Trials, the Executive Summary of safety information produced for international regulators, such as a Development Safety Update Report (DSUR), may serve as the annual safety report sent to HRECs (a full DSUR is not required). The timing of the annual safety report may be aligned with the reporting cycles of global companies or aligned with the annual progress report sent to the HREC.
Child	Minor / young person / person under 18 years. ('Child' will be used throughout this guide)
Clinical Trial	Any research study that prospectively assigns human participants or groups or humans to one or more health-related interventions to evaluate the effects on health outcomes.
CRF	**Case report Form** - A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.
CTA or CTRA	**Clinical Trials Agreement** also referred to as **Clinical Trial Research Agreement** - An agreement governing the safety and efficacy of outside collaborators, proprietary biologics or pharmaceutical compounds in clinical studies.
CTN	**Clinical Trials Notification** - A notification scheme whereby all material relating to the proposed trial, including the trial protocol is submitted directly to the HREC by the researcher

	at the request of the sponsor. The HREC is responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device and the ethical acceptability of the trial process, and for approval of the trial protocol. CTN trials cannot commence until the trial has been notified to the TGA and the appropriate notification fee paid.
CTX	**Clinical Trials Exemption** - An approval process whereby a sponsor submits an application to conduct clinical trials to the TGA for evaluation and comment. A TGA Delegate decides whether or not to object to the proposed Usage Guidelines for the product. If an objection is raised, trials may not proceed until the objection has been addressed to the Delegate's satisfaction. If no objection is raised, the sponsor may conduct any number of clinical trials under the CTX application without further assessment by the TGA, provided use of the product in the trials falls within the original approved Usage Guidelines. A sponsor cannot commence a CTX trial until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted.
CV	**Curriculum vitae -** is a written overview of someone's life's work. Vitae often aim to be a complete record of someone's career, and can be extensive.
Delegate	A person delegated specific but appropriate tasks in relation to the conduct of a research project. Delegation must be evidenced in writing.
Deviation	Any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol.
DSMB	**Data Safety Monitoring Board** - An independent and multidisciplinary group established by the trial sponsor to review, at intervals, accumulating trial data, in order to monitor the progress of a trial and to make recommendations on whether to continue, modify or stop the trial for safety or ethical reasons.
DSMB Charter	A document that defines the primary responsibilities of the DSMB, its relationship with other trial components, its membership, and the purpose and timing of its meeting.
ERM	**Ethical Review Manager -** is an information management system for all ethics and research governance, throughout the life of a research project
HREA	**The Human Research Ethics Applications -** is a streamlined and contemporary ethics application that uses dynamic content and guidance to assist researchers consider and address the principles of the National Statement on Ethical Conduct in Human Research.
HREC	**Human Research Ethics Committee** - A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

HREC Review Only Indemnity	For use where the Indemnified Party is providing ethical review for a multicentre clinical Study where the ethical review will be adopted by hospitals, institutions or sites that are independent from the Indemnified Party, OR as a Reviewing HREC for a single centre study at a hospital or institution that is independent from the Indemnified Party. For use where the Indemnified Party is providing ethical review for a multicentre clinical Study where the ethical review will be adopted by hospitals, institutions or sites that are independent from the Indemnified Party, OR as a Reviewing HREC for a single centre study at a hospital or institution that is independent from the Indemnified Party
IB	**Investigational Brochure -** is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human participants.
ICAO	**International Civil Aviation Organization** - A specialized agency of the United Nations which sets international standards and regulations necessary for the safety, efficiency and regularity of air transport.
ICH GCP	**Good Clinical Practice provided by the International Council for Harmonisation** - A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of human research studies that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of research participants are protected.
Infectious substances	Those substances which are known to contain, or are reasonably expected to contain, pathogens.
Investigational medical device	Medical device being assessed for safety or performance in a clinical investigation.
Investigational medicinal product	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Investigator	An individual responsible for the conduct of a research study at a site ensuring that it complies with GCP guidelines. If a study is conducted by a team of individuals at a site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.
Investigator initiated trial or study	A clinical trial or study that is undertaken by the investigator whereby the investigator and/or their institution takes on the role of the sponsor in addition to their role as investigator.
Master File	(also known as regulatory binder, essential documents folder, site master file, investigator file and site file) - The Master File contains essential documents for a research study that may be

	subject to regulatory agency oversight. In the event of an audit by the TGA, Northern Health Research Governance Office, or other regulatory body this folder will be requested to be reviewed.
Medical Research Practitioner	The Act only allows a 'medical research practitioner' to perform a medical research procedure on a person who does not have decision-making capacity.
Medical Research Procedure	A 'medical research procedure' that requires consent in accordance with the Act is a procedure carried out for the purposes of medical research, including as part of a clinical trial, the administration of pharmaceuticals or the use of equipment or a device. A 'medical research procedure' does not include: - Any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision); - Observing a person's activities; - Undertaking a survey; or - Collecting or using information, including personal information (within the meaning of the Privacy and Data Protection Act 2014) or - Health information (within the meaning of the Health Records Act 2001).
Medical Treatment Decision Maker	Someone who is appointed to make medical treatment decisions on behalf of a person when they no longer have decision making capacity. More than one person may be appointed as a medical decision maker, but only one medical treatment decision maker will have the authority to make a medical decision. Once a medical treatment decision maker is required to make a decision, they may access necessary medical records to make a properly informed decision.
Monitoring	The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Monitoring Plan	A document that describes the strategy, methods, responsibilities, and requirements for monitoring a trial.
NH LREC	**The Northern Health Low Risk Ethics Committee -** provide ethical review of NH initiated single site low risk research projects
NHOR	**Northern Health Office of Research**
NMA	**National Mutual Acceptance scheme -** is a national system for mutual acceptance of scientific and ethical review for multi-centre clinical trials conducted in publicly funded health services.
NOK	**Next of Kin** - may assume various responsibilities once a person is deceased.
PI	**Principal Investigator** - The person primarily responsible for the conduct of the research study. The Principal Investigator at Northern Health must be a Northern Hospital employee or honorary at Northern Health

PICF	**Participant Information & Consent Form -** require Local Sponsors and any person or organisation to whom a trial participant's personal information is transferred to comply with Australian privacy laws, the Health Records Act 2001 (Vic) and where applicable the Victorian Privacy and data Protection Act 2014 (Vic).
Progress & Final Reports	It is the responsibility of the researcher to submit an annual report as per ethical/research governance approval letters. An annual progress report must be submitted for the duration of the project. A comprehensive Final Report is required to submit to the reviewing HREC and local RGO upon completion of the project.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations and organisation of a research project.
Protocol deviation	A less serious non-compliance with the approved study protocol and generally does not impact on participant safety.
Protocol violation	A failure to comply with the study protocol as approved by the Ethics Committee. A violation is a serious non-compliance with the protocol that can affect participant safety & integrity of the study.
QI & QA	**Quality Improvement** – also known as Quality Assurance. An organised process that evaluates, assesses and seeks to improve health service delivery to improve patient and population outcomes and health service efficiency. An audit does not involve the collection of new raw data (other than information that would ordinarily be collected as part of patient management) from a patient either in person, through a survey/questionnaire nor can it be instigated by an external person.
RGO	**Research Governance Officer**
SADE	**Serious Adverse Device Event** - A device-related serious adverse event.
SAE	**Serious Adverse Event** - **device** - Serious Adverse Event for medical devices: any adverse medical occurrence that: Led to a death; Led to a serious deterioration in health of a patient user or other.
SAE	**Serious Adverse Event** - **drug** - Any untoward medical occurrence that, at any dose: - results in death; - is life-threatening;
Serious Breach	A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree: The safety or rights of a trial participant, or The reliability and robustness of the data generated in the clinical trial. Note: this guidance's definition of serious breach differs from the definition in the Australian Code for the Responsible Conduct of Research and is about deviations from the requirements of Good Clinical Practice or the clinical trials protocol
Source Document	Original documents (where the data was first recorded), data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or

	evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial or study).
SOP	**Standard Operating Procedures -** A standard operating procedure is a set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial or study.
SSA	**Site Specific Assessment /Research Governance** - Research governance is a framework for institutions to use to ensure that research is conducted responsibly and safely and is scientifically and ethically sound. Research governance considers legal compliance, financial management, accountability and risk management associated with research at a participating site. Research governance is administered by the process of submission of a site specific assessment (SSA) application.
SSI	**Significant Safety Issue** - A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
SUSAR	**Suspected Unexpected Serious Adverse Reaction** - is an adverse reaction that is not consistent with the product information
Suspected Breach	A report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.
TALS	**Transcultural and language Service** - Northern Health department of Transcultural and Language Service.
TGA	**Therapeutic Goods Administration** - Australia's regulatory agency for medical drugs and devices.
TransCelerate mutually recognised ICH GCP training	The minimum standards as defined by TransCelerate Biopharma Inc. for Good Clinical Practice training.
Urgent Safety Measure	A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
VCAT	**Victorian Civil and Administrative Tribunal -** is a tribunal that hears and decides civil and administrative legal cases in the State of Victoria, Australia
VMIA	**Victorian Managed Insurance Authority** - Victorian statutory authority for the provision of insurance and risk advice and cover for Vic State entities.

VSM	**Victorian Specific Module -** In Victoria there is a requirement to comply with legislation relevant to human research involving information privacy (Privacy and Data Protection Act 2014), health information (Health Records Act 2001).
Witness	An individual who is not a member of the research team, who is present during the consent process and signs the consent documents attesting that the person who they believe to be the participant has freely signed the informed consent documents. An interpreter cannot act as a witness to the consent process.